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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,785	11/29/2001	Alex Azhayev	005416.00004	9129

22907 7590 01/13/2003

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,785

Applicant(s)

Azhayev et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-63 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1639 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-44 and 45-53 *in part*, drawn to an support/article that has the formula depicted in claim 1 (i.e. $X = (=O)$ and $Y = NH$ in the formula of claim 45), classified variously depending on the ultimate structure, for example, class 564, subclasses 177 or 186.
 - II. Claims 45-53 *in part*, drawn to an article that has $X = (=O)$ and $Y = O$ in the formula of claim 45, classified variously depending on the ultimate structure, for example, class 560, subclass 8.
 - III. Claims 45-53 *in part*, drawn to an article that has $X = S$ and $Y = O$ in the formula of claim 45, classified variously depending on the ultimate structure, for example, class 568, subclass 275.
 - IV. Claims 45-53 *in part*, drawn to an article that has $X = S$ and $Y = NH$ in the formula of claim 45, classified variously depending on the ultimate structure, for example, class 564, subclass 102 or class 568, subclass 61.
 - V. Claims 45-53 *in part*, drawn to an article that has $X = NH$ and $Y = O$ in the formula of claim 45, classified variously depending on the ultimate structure, for example, class 568, subclass 579 or class 564, subclass 305.
 - VI. Claims 45-53 *in part*, drawn to an article that has $X = NH$ and $Y = NH$ in the formula of claim 45, classified variously depending on the ultimate structure, for example, class 564, subclasses 305 or 461.

VII. Claims 54-63, drawn to a method for releasing a product oligonucleotide from a support, classified variously, for example, class 536, subclass 25.31.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I – VI represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, each of the products has a *different chemical structure* defined by the different X and Y moieties.

4. Groups I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support/article of Group I could be used in myriad different methods for solid supported synthesis of compounds *different from* oligonucleotides. The method of Group VII requires a “product oligonucleotide” attached to a solid support.

5. Groups II – VI are not related to Group VII. The inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects. In the instant case, each of the articles of Groups II – VI are not used in the method of Group VII.

6. Therefore, the groups that describe these inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group could support a separate patent.

7. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different inventions would require different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

8. This application contains claims directed to patentably distinct species of the claimed invention for **all of Groups I – VII**. Election is required as follows.

9. If applicant elects the invention of ***any of Groups I – VI***, applicant is required to elect from the following patentably distinct species. Claim 54 is generic to each group.

Species of support/article

Applicant is required to elect, for purposes of search, a *single, specific* support material/article. The variable moieties A, B and C must be specifically defined for the elected species, resulting in a *single elected chemical formula*.

Also, to be fully responsive, applicant must provide a list of the claims readable on the elected species. See also paragraph 12 below.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

10. If applicant elects the invention of **Group VII**, applicant is required to elect from the following patentably distinct species. Claims 54-56 are generic.

Species of supported oligonucleotide used in the method

Applicant is required to elect, for purposes of search, a *single, specific* supported oligonucleotide used in the claimed method. The variable moieties A, B and C must be specifically defined for the elected species, resulting in a *single elected chemical formula*.

Also, to be fully responsive, applicant must provide a list of the claims readable on the elected species. See also paragraph 12 below.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is

complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306- 3217. The fax phone number

for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
January 10, 2003

A handwritten signature in black ink, consisting of stylized, cursive letters that appear to read 'MGB' followed by a long horizontal flourish.

**MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER**



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Maurie Garcia Baker, Ph.D.

ART UNIT: 1639

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

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